



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 1, 2015

Merits Health Products Company, LTD
Vincent Chen
Manager, R&D Department
No. 18, Jingke Road, Nantun District,
Taichung City, Taiwan 40852

Re: K142162

Trade/Device Name: Merits Transformer Power Scooter, S941

Regulation Number: 21 CFR 890.3800

Regulation Name: Motorized Three-Wheeled Vehicle

Regulatory Class: Class II

Product Code: INI

Dated: March 25, 2015

Received: March 31, 2015

Dear Mr. Chen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Felipe Aguel -S
for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K142162

Device Name

Merits Transformer Power Scooter, S941

Indications for Use (Describe)

The Merits Transformer Power Scooter, S941, is to provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Merits Health Products Co., LTD.
510(k) Premarket Notification

Submitter:

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Contact Person:

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Date Prepared:

July 30, 2014

Proprietary Name:

Merits Transformer Power Scooter, S941

Common name:

Four Wheel Power Scooter

Classification name:

Physical Medicine / Motorized Three – Wheeled Vehicle (21 CFR 890.3800)

Product Code:

INI

Comparison to Predicate Devices:

This submission indicates the Substantial Equivalence of the Merits Transformer Power Scooter, S941, with the predicate Merits Travel Ease Electric Scooter, Pioneer 4 (K011753). S941 has the same intended uses and similar indications, technological characteristics and principles of operation with predicate device.

Device Description

The Merits Transformer Power Scooter, S941, is battery powered, rear transaxle driven and is controlled by the Dynamic Rhino-2 120amp controller. The user interface is a throttle lever and control buttons on the control panel. S941 is powered by two 12 VDC 50ah (22NF) batteries. The batteries are charged by 5A off-board charger connect with 3-pin Microphone Connector to charging socket on Tiller. The approximate driving range on fully charged batteries is up to 40km (25mi). The scooter frame is a welded steel construction and includes 2 rear wheels with drive units (including motor, gear box, and brake), batteries, 2 front wheels and a tiller to control its turning direction. When the user activates the throttle lever, the controller receives a signal to release the brakes. With the brakes released, the scooter is allowed to move forwards or backwards. When the user releases the throttle lever, the scooter slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user stop by letting go of the throttle lever. The upholstery of the device complies with ISO 7176-16:2012 Resistance to ignition of postural support devices.

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The Merits Transformer Power Scooter, S941, is substantially equivalent to the Merits Travel Ease Electric Scooter, Pioneer 4 (K011753). Both products are battery power, motorized vehicles designed for use as personal power mobility aids. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair. Additional, they are all constructed from the same basic materials, have the same basic operational principles and all use DC batteries as their source of power.

Although there are some minor differences between S941 and its predicate device. But they raise no new issues of safety or effectiveness. Performance data demonstrate that S941 is safe. The non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Intended Use

The Merits Transformer Power Scooter, S941, is to provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

Discussions of Non-clinical Tests Performed for Determinations of Substantial equivalence are as follows:

- ISO 7176-1:1999 Determination of Static Stability
- ISO 7176-2:2001 Determination of Dynamic Stability of electric wheelchairs
- ISO 7176-3:2012 Determination of effectiveness of brakes
- ISO 7176-4:2008 Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5:2008 Determination of overall dimensions, mass and maneuvering space
- ISO 7176-6:2001 Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7:1998 Method of Measurement of Seating and Wheel Dimensions
- ISO 7176-8:1998 Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-9:2009 Climatic tests for wheelchairs
- ISO 7176-10:2008 Determination of obstacle-climbing ability of electrically power wheelchairs
- ISO 7176-11:2012 Test dummies
- ISO 7176-13:1989 Determination of coefficient of friction of test surfaces
- ISO 7176-14:2008 Power and control systems for electrically powered wheelchairs and scooter- Requirements and test methods.
- ISO 7176-15:1996 Requirements for Information Disclosure, Documentation and Labeling
- ISO 7176-16:2012 Resistance to ignition of postural support devices
- ISO 7176-21:2009 Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

Conclusions

According to comparison table, the differences on weight capacity, speed, battery size and dimensions do not deleteriously affect the safety and effectiveness of the device.

So based on the design, performance specifications and testing and intended use, the Merits Transformer Power Scooter, S941, is substantially equivalent to the Merits Travel Ease Electric Scooter, Pioneer 4 (K011753).